No. 2015-1067

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

INOVA LABS, INC.

Appellant

v.

INOGEN, INC.,

Appellee

Appeal from the United States Patent and Trademark Office
Patent Trial and Appeal Board
In Reexamination No. 95/001,885

APPELLANT'S REPLY BRIEF

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Inova Labs, Inc. v. Inogen, Inc.

No. 15-1067

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) appellant certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Inova Labs, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Inova Labs, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. ☑ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Eric B. Meyertons
Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C.

2/20/15
Date

/s/Eric B. Meyertons
Signature of counsel

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Printed name of counsel

Please Note: All questions must be answered
cc: Appellee's counsel of record (via CM/ECF)

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RESPONSE TO INOGEN'S ARGUMENTS

If a problem is known in the prior art, and a prior art apparatus, in the same field of endeavor, exists that can address such problem, then would it have been obvious to a person of ordinary skill in the art to use the apparatus to address the problem? Appellant/Inova says "yes" and Appellee/Inogen says "no." The Board, however, never fully considered this question. Therefore, the issue before this Court is whether the Board engaged in sufficient factual determinations to support its finding of non-obviousness of claims 1-3 of U.S. Patent No. 7,841,343 to Deane et al. ("the '343 Patent") and, within its non-obviousness analysis, whether a legally complete non-obviousness analysis that accounted for all facts in the record was conducted.

Specifically, it is uncontested that all the structural elements of claim 1 are disclosed in U.S. Patent No. 4,986,269 to Hakkinen ("Hakkinen"), including an adjustable potentiometer. Where the parties disagree is whether the disclosed potentiometer is capable of user adjustment. Appellant/Inova contends that the Board erred when it concluded that Hakkinen on its face does not disclose user adjustability and, effectively, ended its non-obviousness inquiry without finding of

facts as to whether either submitted expert testimony or the Admitted Prior Art (the "APA") gave adequate motivation to combine user adjustability with the disclosed potentiometer. Inova thus seeks clarification of the scope of the Board's obligation as a fact finder under a non-obviousness inquiry, as well as whether the Board met its obligations in considering the evidence and arguments with respect to the claims at issue in this appeal.

Appellee/Inogen in its brief focuses on various motivations to combine. As discussed at length below, this Court recently observed that the motivation for one of ordinary skill in the art to combine various elements need not be the motivation(s) considered by the inventor. Liberated of that false constraint, a review of the factual record shows that it is replete with motivations to combine—even if they may not be to the liking of a particular expert—and Inova contends that these motivations were not properly considered by the Board.

1. Response to Inogen Arguments VI(A)(1) and VI(A)(2) No New Arguments Have Been Presented

Inogen incorrectly alleges that Inova is relying on new arguments not presented to the Board. Specifically, Inogen incorrectly alleges that "Inova failed to raise with the Board its current argument that Claims 1-3 would have been

obvious even if user selectable threshold pressure levels were not disclosed in the prior art." Inogen Brief at 16.

In fact, however, no new arguments were set forth in Inova's appeal. In Inova's appeal of the Examiner's failure to adopt Inova's proposed rejection of the claims, Inova presented the following arguments:

> Thus, based on the teaching of the APA, and given that Hakkinen's potentiometer enables the user to adjust the threshold pressure level, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hakkinen by using the potentiometer to set the breath pressure threshold to a lower level during sleep and to a higher level during normal daytime activity, thereby ensuring that the oxygen delivery system will provide both accurate breath detection during sleep as well as efficient oxygen delivery during normal activity.
>
> Further, based on the teaching of the APA, and given that Hakkinen's computer can be programmed to control therapeutic variables, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hakkinen by using the computer to adjust the breath pressure threshold between a lower level during sleep and a higher level during daytime activity, thereby ensuring that the oxygen delivery system will provide both accurate breath detection during sleep as well as efficient oxygen delivery during normal activity.

See A463 at second paragraph (emphasis added). Thus, contrary to the allegations of Inogen, Inova did raise the issue that Claims 1-3 would have been obvious even if user selectable threshold pressure levels were not disclosed in the prior art.

Furthermore, Inogen's allegations highlight the problems with the decision of the Board. In the Board's decision, the Board focused on only one of the many proposed rejections set forth in Inova's appeal. The Board took the position that the potentiometer of Hakkinen did not qualify as a "user-selectable" device. Since the potentiometer did not qualify as a "user-selectable" device, the claims were incorrectly deemed to be patentable over the cited art by the Board. In coming to this conclusion, the Board states that:

> Without determining whether or not Hakkinen is limited to factory adjustment, the proper inquiry is whether the potentiometer is capable of *user* adjustment and Hakkinen is silent regarding whether a user would use the potentiometer to adjust the settings as claimed. There is simply insufficient disclosure in Hakkinen regarding the function of the potentiometer to glean that it could operate to allow *user selectability* in the manner suggested by [Inova] to meet the claimed limitation.

See A22 (underline added). This is plainly wrong since Hakkinen's silence on who uses the Hakkinen potentiometer should not be construed as a limit to its teachings. Instead, such silence simply means that Hakkinen put no limit at all as to who would use such a potentiometer.

In addition, the Board appears to be addressing Inova's first argument (as presented above) but fails to address the second argument that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hakkinen by using the computer to adjust the breath pressure threshold as set forth in the claims. This omission is reversible error because it reveals that the Board did not engage in a legally adequate finding of facts as to whether the other evidence in the record supports a finding of potentially alternative motivations to combine. In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (this Court reviews the Board's factual findings for substantial evidence and its legal conclusions de novo). Additionally, the Board did not find that either Hakkinen or the APA teaches away from user adjustability. This is notable as this Court has previously observed that its "precedent, however, does not require that the motivation be the *best* option, only that it be a *suitable* option from which the prior art did not teach away." Par Pharm., Inc. v. TWi Pharms., Inc. 773 F.3d 1186, 1197–98 (Fed. Cir. 2014). (citing Galderma Labs., L.P. v. Tolmar, Inc., 737 F.3d 731, 738 (Fed. Cir. 2013); Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.., 713 F.3d 1369, 1376 (Fed. Cir. 2013)). Thus, the Board's inquiry was facially insufficient when it failed to consider whether Inova had demonstrated that a skilled artisan would have had a suitable motivation to combine the teaching of a potentiometer

with user adjustability, instead stopping at its finding that Hakkinen is *silent* as to user adjustability.

2. Response to Inogen Arguments VI(B)(1)
K/S HIMPP is Not Relevant

Inogen incorrectly argues that this case is distinguishable from KSR on the basis of the Court's decision in K/S HIMPP, 751 F.3d at 1366. We disagree.

In K/S HIMPP the Court was faced with a non-analogous situation. In K/S HIMPP the Court affirmed the claims on the basis that the Examiner failed to provide any documentary evidence to prove purportedly well-known facts. K/S HIMPP, pg. 6. The patent in suit in K/S HIMPP was directed to a hearing aid with three main parts: a behind-the-ear audio processing module, an in-the-canal module, and a connector between the modules. One of the claims at issue, claim 3, included the feature that the insulated wiring portion is terminated by a plurality of prongs that provide a detachable mechanical and electrical connection to an audio processing module. The Examiner, in rejecting the claims, stated that providing a plurality of prongs for the electrical connections or for the plugs is known in the art, but failed to provide factual support for this assertion. K/S HIMPP at pg. 3. The current case differs from K/S HIMPP in that factual support exists for each of the physical components of the claims at issue.

As set forth in Inova's Opening Brief, Hakkinen discloses a potentiometer that can be adjusted by anyone to change the inhalation pressure set points. See A50 at 11:46-50. Hakkinen specifically discloses controlling therapeutic values with a computer. See A48-A49 starting at 8:68. Hakkinen also discloses allowing the inhalation pressure that triggers oxygen to be controlled (which means reduced or increased) using the potentiometer. See A50 at 11:46-50. Unlike in K/S HIMPP, the necessary physical components are disclosed and supported by factual support. The ruling set forth in K/S HIMPP does not apply in this case.

3. Response to Inogen Arguments VI(B)(2) All Components Necessary to Create the Claimed System are Factually Supported by Hakkinen

As noted above, Hakkinen discloses all of the physical components of the claimed device set forth in the '343 Patent. The APA teaches that that it was well known at the time of the invention that: (1) during sleep, the patient's breathing generates lower breath pressure, requiring the need for a lower breath pressure threshold in order to accurately detect breathing when the patient is asleep; (2) a lowered breath pressure threshold, while needed during sleep, is not desired during normal daytime patient activity, and (3) the inhalation breath pressure level setting

should not be set too high or too low. See A12 at 1:65 – 2:32. Thus, as Inova presented to the Board, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hakkinen by using the computer to adjust the breath pressure threshold between a lower level during sleep and a higher level during daytime activity, thereby ensuring that the oxygen delivery system will provide both accurate breath detection during sleep as well as efficient oxygen delivery during normal activity.

As noted in KSR, "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." 550 U.S. at 421, 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. at 420, 82 USPQ2d at 1397. One may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. at 418, 82 USPQ2d at 1396.

The very small adjustment of connecting the computer of Hakkinen to the potentiometer of Hakkinen to allow a user to adjust the inhalation breath pressure level settings is well within the inferences and creative steps that a person of ordinary skill in the art would employ, as noted in KSR.

As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in Graham v.

John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

> (A) Determining the scope and content of the prior art; and
>
> (B) Ascertaining the differences between the claimed invention and the prior art; and
>
> (C) Resolving the level of ordinary skill in the pertinent art.

In this case, the level of ordinary skill in the pertinent art can be readily ascertained by the teachings of the '343 Patent (i.e., the patent being reexamined). As we previously noted, the '343 Patent, when explaining the implementation of the "day" and "night" modes only teaches that "a user input to the controller" may be added to the system. See A15 at 7:14-17. The fact that the '343 Patent deems details concerning such implementation unnecessary for enablement of the invention indicates that a person of ordinary skill in the art at the time of the invention was well aware of many techniques to allow a user to alter the sensitivity of the pressure sensors. Thus, the '343 Patent teaches that a person of ordinary skill in the art, presented with the concept of the need to alter the threshold

pressure level based on the activity level of the user, would not need any further teachings to implement the concept.

Inogen wrongly attempts to denigrate Inova's efforts to ascertain the level of ordinary skill in the pertinent art by claiming that Inova failed to raise an enablement rejection to the Board. The rules under the pre-AIA guidelines preclude raising the issue of enablement of unamended claims in reexamination proceedings. 35 U.S.C. 311 (pre-AIA)(a). Furthermore, Inova's use of the '343 Patent to support their findings regarding the level of ordinary skill in the pertinent art is different from a finding of lack of enablement. Inova is simply relying on what the inventors of the '343 Patent would consider sufficient to allow other people of ordinary skill in the art to practice the claimed invention.

4. Response to Inogen Arguments VI(B)(3)
The Prior Art Provides Sufficient Motivation to Combine the Known Elements

Inogen incorrectly claims that, even if all of the components used to implement the invention were known in the prior art, the claims are not necessarily obvious. Inogen then cites an incomplete citation of KSR to support their position. The full citation is cited below, with the important left-out portion underlined.

As is clear from cases such as Adams, a patent composed of several

> elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."

KSR, 82 USPQ2d at 1396. Hakkinen discloses all of the components necessary to create the claimed invention. The APA provides the reason for combining the elements of Hakkinen in the manner set forth in the claims. Inova's analysis is therefore supported by the Supreme Court's teachings in KSR.

Furthermore, this Court recently observed in Par Pharm., Inc. v. TWi Pharms., Inc., cited by Inogen in its briefing:

> [W]e are not limited to the same motivation that may have motivated the inventors. Alcon, 687 F.3d at 1369 ("We have repeatedly held that the motivation to modify a prior art reference to arrive at the claimed invention need not be the same motivation that the patentee had."). We have explained that "that "[m]otivation to combine may be found in many different places and forms." Allergan, Inc. v. Sandoz, Inc., 726 F.3d 1286, 1292 (Fed. Cir. 2013); see also Alza, 464 F.3d at 1294 (stating that the motivation to combine does not have to be explicitly stated in the prior art, and can be supported by testimony of an expert witness regarding knowledge of a person of skill in the art at the time of invention).

773 F.3d at 1197 (Fed. Cir. 2014). Furthermore, "Our precedent, however, does

not require that the motivation be the *best* option, only that it be a *suitable* option from which the prior art did not teach away." Id. at 1197–98 (citations omitted). In this vein, even if Hakkinen himself was not motivated to combine his potentiometer with user selectable functionality, that does not foreclose a finding that one of ordinary skill in the art would be motivated to perform such a combination. Again, the Board's failure to consider alternative motivations offered by Inova, constitutes reversible error in that the Board did not come to *any* conclusions on the issue.

5. Response to Inogen Arguments VI(B)(4)
The Obviousness of the Claims is not Based on Hindsight

Inogen incorrectly argues that the Inova's obviousness analysis is based on improper hindsight reasoning. However, "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA1971).

The APA teaches that there is need for a lower breath pressure threshold in order to accurately detect breathing when the patient is asleep. It is obvious that

the user will be aware when they are going to go to bed to sleep. Allowing the user to switch the threshold breath pressure level to a lower level is obviously the most efficient way of ensuring that the threshold breath pressure level is used during nocturnal sleep. For the hypothetical person of ordinary skill in the art, when confronted with the problem of ensuring that the breath pressure threshold is set to the appropriate sensitivity when the patient is sleeping, implementing user selection of the selectivity is an obvious approach to take, without any hindsight gleaned from reading the specification of the '343 Patent, and especially in view of the APA.

Inogen incorrectly alleges that the device taught by Hakkinen is intended for patients who are very ill, weak, and unconscious. Inogen's characterization of Hakkinen is not accurate. The portion of Hakkinen cited by Inogen states:

> Basically, the present invention is directed to a respiration therapy apparatus intended for persons suffering from respiratory diseases, for indisposed persons, or for unconscious persons, and which is used as a respirator (IPPB) and/or as drug atomizing means and/or as oxygen dispensing means conforming to the patient's respiration.
> (See A46 at 3:9-15)

Inogen's position that Hakkinen is intended for patients who are "very ill" is misleading at best. Chronic obstructive pulmonary disease (COPD) is a "respiratory disease" that is characterized by shortness of breath. See A588.

COPD is a very common disease that would benefit from an "oxygen dispensing means conforming to the patient's respiration" as set forth in Hakkinen. Many patients suffering from COPD can walk, talk, and function (albeit more slowly than a patient without COPD), and thus would not be considered so "very ill" that they would not be physically capable of adjusting a setting on a conserving device. We reiterate that the motivations set forth in Hakkinen, such as they exist, do not control the analysis; the Court is not limited to the same motivation that may have motivated the inventors. Par Pharm., Inc., 773 F.3d at 1197. The correct legal inquiry is whether "a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so." Id. at 1193 (citations omitted).

6. Response to Inogen Arguments VI(C)(1) Hakkinen Teaches that the Threshold Pressure Levels Need to Be Selected Based on the Needs of the User

Inogen falsely argues that Hakkinen does not expressly teach user selectability. However, Inogen ignores the fact that Hakkinen teaches that the threshold pressure levels need to be adjusted. Part of Inogen's argument focuses

on the alleged teaching that Hakkinen was intended for use with person's that are physically incapable of adjusting the settings of the device. As discussed in our previous section, this argument is not true.

The section of Hakkinen related to the intended uses of the device, however, shows that the device of Hakkinen must have allowed some alteration of the threshold pressure levels after the device left the factory. As noted above, Hakkinen teaches that apparatus is intended for persons suffering from respiratory diseases, for indisposed persons, or for unconscious persons. Each of these groups of people will exhibit different breath pressures during inhalation. For example, the person suffering from a respiratory disease, such as COPD, will have a much higher inhalation breath pressure than an unconscious person. In order to prevent delivery of oxygen at the wrong time (or failure to deliver oxygen at the correct time) the threshold pressure levels must be adjusted for each group of persons. By incorporating a potentiometer into the design of the device, Hakkinen provides a means for making these necessary adjustments. Since the condition of the user who would be purchasing the device would not generally be known at the time of manufacture, Hakkinen provides a means that allows a user (or caregiver) to set the threshold pressure levels for the appropriate condition of the patient.

7. Response to Inogen Arguments VI(C)(2)
Inherency is not a relevant issue for the present analysis

Inova has not raised the issue of inherency and thus Inogen's arguments regarding inherency are irrelevant. Inogen notes, however, that Hakkinen discloses that the device is intended for use with persons having very different inhalation breath pressures. As discussed above, this at least suggests that there is some way of adjusting the threshold pressure levels after the Hakkinen device was manufactured.

8. Response to Inogen Arguments VI(C)(3)
Inova's arguments show that the claimed invention is obvious

Inogen has already addressed the issues raised in this argument in sections 3 and 4 above.

9. Response to Inogen Arguments VI(D)(1) and VI(D)(2)
The Admitted Prior Art suggests user selectable threshold pressure levels

As noted above, the Board incorrectly took the position that the potentiometer of Hakkinen did not qualify as a "user-selectable" device because "there is simply insufficient disclosure in Hakkinen regarding the function of the

potentiometer to glean that it could operate to allow *user selectability* in the manner suggested by [Inova] to meet the claimed limitation." See A22. The Board did not rule, as Inogen implies, that the APA fails to teach or suggest user selectable threshold pressure levels. In fact, the Board is particularly silent regarding the APA. The APA, as discussed above, provides motivation to the person of ordinary skill in the art to allow a user, the person who can best anticipate when the breathing pattern will change, to change the threshold pressure level.

Inogen further argues that the APA discourages allowing a user to change the threshold pressure levels. The section of the APA cited by Inogen discusses the need to tune the threshold pressure to be as high as possible to detect breathing events but to also be low enough to avoid false firing. See A12 at 2:12-15. Inogen contends that this suggests that a user should not be allowed to "disrupt the careful balance" identified in the APA.

In the Declaration of Taisto Hakkinen, Mr. Hakkinen notes that the potentiometer described in Hakkinen provides a "continuous range of variable resistance." See A104 at ¶11. As such, contrary to Inogen's arguments, Hakkinen's potentiometer would be particularly suitable for allowing a user to

maintain the careful balance set forth in the Admitted Prior Art. This parallels this Court's finding in Par Pharm.

10. Response to Inogen Arguments VI(D)(3) Inova did not improperly characterize the prior art

Inogen incorrectly argues that Inova's arguments obfuscates an important issue. The issue that Inogen contends is misinterpreted is that knowing that a patient's physiological inspiration pressure may be different at night is not the same as knowing that a device's threshold pressure level should be different at night. With respect to this feature, the APA teaches:

> Moreover, during sleep, some patients are shallow and/or irregular breathers, such that nighttime breathing for these patients may not generate enough vacuum pressure to trigger bolus delivery. In some cases, due to irregular breathing patterns, the conserver may not detect every breath, resulting in breath skipping. In either of these cases, a bolus may not be triggered often enough to deliver enough oxygen to the patient over time.

See A12 at 2:21-28. From the passage it is clear that the APA recognized that having the threshold breath pressure set too high can create a situation in which the patients, at night, will not provide sufficient vacuum pressure to trigger the bolus delivery. This teaching suggests the obvious solution – i.e., to adjust the threshold breath pressure to compensate for the change in inspiration pressure. Moreover,

Hakkinen provides an apparatus with a potentiometer (e.g., a knob) that can do just that.

Inogen's incorrect contention that a person of ordinary skill in the art would not recognize this as an appropriate reaction to the changing inspiration pressure goes against the common sense teachings that the Supreme Court promotes in KSR. In KSR the Supreme Court explains that:

> [w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

The small adjustment from knowing that the inspiration pressure is lower in patients at night to adjusting the threshold breath pressure to compensate for the lower inspiration pressure is the type of common sense revelation that the Supreme Court has ruled is not innovative. Stated another way, with the knowledge that the APA provides, it would be completely obvious to simply use the apparatus in Hakkinen to adjust the inspiration pressures to be different at night versus daytime.

11. Response to Inogen Arguments VI(E)
Claim 2 is obvious in view of the cited art

Claim 2 includes the limitations that (1) the different levels of threshold breath pressure comprise two user-selectable levels, representing a night mode and a day mode and (2) the actual values of each level are determined by the patient's caregiver. Both of these features are taught by the combination of Hakkinen and the APA. The APA teaches that:

> In addition, conserving devices typically deliver a pre-determined volume of gas in response to patient breath demand. During sleep, the normal daytime trigger levels may be too high, and the associated bolus volumes may not be adequate to maintain required blood oxygen saturation levels.

See A12 at 2:16-20. This passage, as well as much of the APA, is devoted to describing the differences between the daytime and nighttime "trigger levels." Thus, the APA specifically calls out the need for at least two modes: a day mode and night mode.

Finally, it is completely obvious to have a caregiver or a patient adjust a medical device. There's nothing inventive about specifying who adjusts a medical device. There's nothing inventive about specifying that the potentiometer knob of Hakkinen is adjusted by a caregiver of a patient, especially since the APA

recognizes the need to have breath threshold pressure adjusted to different levels between day and night.

The second feature of this claim refers to the actual values of each (breath pressure) level are determined by the patient's caregiver. With respect to this feature, the '343 Patent teaches:

> Alternatively, access to the sensitivity settings may be more difficult, designed such that the actual values are selected by the patient's caregiver.

See A13 at 3:18-20. Inogen argues that a person of skill in the art would have no reason to rearrange the circuitry of Hakkinen so that a computer can be used to control the potentiometer. As discussed in section 3 above, such a modification is obvious in view of the teachings of Hakkinen.

12. Response to Inogen Arguments VI(F)(1) Aylsworth provides additional support for the APA

Contrary to the Inogen's allegations, Aylsworth clearly teaches the need to lower the threshold pressure levels to accommodate sleeping patients. For example, Aylsworth teaches:

> It is common to use diaphragm-based sensors to detect patient inhalations. … These sensors work quite well at short distances between a patient and the sensor (provided the patient is not asleep or mouth breathing) usually up to distance (sic) of about 7 feet from the patient's nose to the sensor.

See A81 at ¶0003. Aylsworth goes on to show that the OM-400 sensor (a diaphragm-based sensor) fails to detect low levels of inhalation. See A83 at ¶0054, last sentence; A84 at ¶0062. Aylsworth then shows that the FLT device, a device which was created by Aylsworth to have increased sensitivity to inhalations was able to detect the inhalations that were "even shallower and thus more difficult to detect" than the inhalations used to test the OM-400 sensor. See A82 at ¶0050 and A84 at ¶0063. Inova's cited teachings of Aylsworth show that what was admitted as prior art in the APA is, indeed, already known in the art.

13. Response to Inogen Arguments VI(F)(2) Hakkinen and Bunnell show the general knowledge of a person of ordinary skill in the art

Neither Hakkinen '832 nor Bunnell were relied upon for the obviousness rejection. Hakkinen '832 and Bunnell were presented to show that the general knowledge of a person of ordinary skill in the art. Specifically, a person of ordinary skill in the art at the time of the invention would understand, and know

how to implement, allowing user selectability of the threshold pressure level by adding a switch (or some other device) that allows a user to set the potentiometer to predefined positions (and thus adjust the threshold breath pressure level) of the system. Inogen's argument against the teachings of these references is based on speculation as to the identity of a user. Simply put, if a device has an input that allows the operating parameters to be changed, such a device is capable of being adjusted by the user (i.e., the person holding, or contacting, the device).

CONCLUSION/STATEMENT OF RELIEF SOUGHT

As has been shown above, claims 1-3 of the ’343 Patent are non-patentable over Hakkinen in view of the APA (or Aylsworth). The PATB clearly erred when they affirmed the Examiner’s decision to allow claims 1-3 in view of the cited art. We respectfully request that the court reverse the ruing of the PATB by confirming that claims 1-3 are directed to unpatentable subject matter.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on February 20, 2015, Inova Labs, Inc.'s Appellant Reply Brief was filed electronically using the CM/ECF system, which will send notification of such filing to counsel of record for Appellee Inogen, Inc. as follows:

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